which is registered under FIFRA section 3;

(vi) Deletion of approved uses of claims;

(vii) Redesign of the label format involving no substantive changes, express or implied, in the directions for use, claims, representations, or precautionary statements;

(viii) Change in the product name or addition of an additional brand name, if no additional claims, representations, or uses are expressed or implied by the changes;

(ix) Clarification of directions for use;

(x) Correction of typographical errors;

(xi) Changes in the registrant's name or address;

(xii) Adding or deleting supplemental registrants;

(xiii) Changes in the package or container size;

(xiv) Changes in warranty, warranty disclaimer, or liability limitation statements, or addition to or deletion of such statements;

(xv) ''Splitting'' a label for the sole purpose of facilitating the marketing of a product in different geographic regions with appropriate labels, where each amended label will contain previously approved use instructions (and related label statements) appropriate to a particular geographic region;

(xvi) Any other type of amendment, if the Administrator or his designee determines, by written finding, that the Agency consideration of scientific data would not be necessary in order to approve the amendment under FIFRA section 3(c)(5); and

(xvii) Compliance with Agency Regulations, adjudicatory hearing decisions, notices, or other Agency announcements that unless the registration is amended in the manner the Agency proposes, the product's registration will be suspended or cancelled, or that a hearing will be held under FIFRA section 6. (However, this paragraph does not apply to amendments designed to avoid cancellation or suspension threatened under FIFRA section 3(c)(2)(B) or because of failure to submit data.)

§ 152.83 Definitions.

As used in this subpart, the following terms shall have the meanings set forth in this section:

Data gap means the absence of any valid study or studies in the Agency's files which would satisfy a specific data requirement for a particular pesticide product.

Data Submitters List means the current Agency list, entitled ''Pesticide Data Submitters by Chemical,'' of persons who have submitted data to the Agency.

Exclusive use study means a study that meets each of the following requirements:

(1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978;

(2) The study was submitted in support of, or as a condition of approval of, the application resulting in the first registration of a product containing such new chemical or new combination (first registration), or an application to amend such registration to add a new use; and

(3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B);

Provided that, a study is an exclusive use study only during the 10-year period following the date of the first registration.

Original data submitter means the person who possesses all rights to exclusive use or compensation under FIFRA section 3(c)(1)(F) in a study originally submitted in support of an application for registration, amended registration, reregistration, or experimental use permit, or to maintain an existing registration in effect. The term includes the person who originally submitted the study, any person to whom the rights under FIFRA section 3(c)(1)(F) have been transferred, or the authorized representative of a group of joint data developers.

Valid study means a study that has been conducted in accordance with the Good Laboratory Practice standards of 40 CFR part 160 or generally accepted

scientific methodology and that EPA has not determined to be invalid.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.84 When materials must be submitted to the Agency.

All information required by this subpart should be submitted with the application, but may be submitted at any later time prior to EPA's approval of the application. The Agency will not approve any application until it determines either that the application is not subject to these requirements or that all required materials have been submitted and are acceptable.

§ 152.85 Formulators' exemption.

(a) *Statutory provision.* FIFRA section 3(c)(2)(D) excuses an applicant from the requirement to submit or cite data pertaining to any pesticide contained in his product that is derived solely from one or more EPA-registered products which the applicant purchases from another person. This provision is commonly referred to as the formulators' exemption.

(b) *Applicability of the formulators' exemption.* (1) The formulators' exemption applies only to data concerning the purchased product or its ingredients. These data may include, but are not limited to, product chemistry, toxicology, residue chemistry, exposure, environmental fate, and ecological effects.

(2) The data to which the formulators' exemption applies usually will concern the safety of one or more of the product's active ingredients, specifically, those active ingredients which are contained in the purchased product. In general, data for which the required test substance is the technical grade of the active ingredient, the pure active ingredient, the radiolabeled pure active ingredient, or a typical end-use product are eligible for the formulators' exemption.

(3) The formulators' exemption generally does not apply to data on the applicant's product itself, including the safety or efficacy of the product, unless the composition of the product is identical to the purchased product. In general, data for which the required test substance is the product proposed for registration are not eligible for the formulators' exemption.

(c) *Limitation of the formulators' exemption.* EPA interprets FIFRA section 3(c)(2)(D) as allowing an applicant to use the formulators' exemption with respect to data concerning an ingredient of his product only if:

(1) The application indicates that the ingredient's presence in the product is attributable solely to the purchase from another person of an identified, registered product containing that ingredient and the use of the purchased product in formulating the product; and

(2) The purchased product is a registered manufacturing-use product whose label does not prohibit its use for making an end-use product labeled for any use for which the applicant's product will be labeled; or

(3) The purchased product is a registered end-use product labeled for each use for which the applicant's product will be labeled.

(d) *Claiming eligibility for the exemption.* (1) If the product contains one or more ingredients eligible for the formulators' exemption, the applicant need not comply with the requirements of §§ 152.90 through 152.96 with respect to any data requirement pertaining to such ingredient, provided that he submits to the Agency a certification statement containing the following information (a form for this purpose is available from the Agency):

(i) Identification of the applicant, and of the product by EPA registration number or file symbol.

(ii) Identification of each ingredient in the pesticide that is eligible for the formulators' exemption, and the EPA registration number of the product that is the source of that ingredient.

(iii) A statement that the listed ingredients meet the requirements for the formulators' exemption.

(iv) A statement that the applicant has submitted (either previously or with the current application) a complete, accurate and current Confidential Statement of Formula.

(v) The name, title and signature of the applicant or his authorized representative and the date of signature.

(2) An applicant for amended registration is not required to submit a